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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/714,511

11/14/2003

William W. Alston

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9835

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7590

08/25/2010

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 101/2
EAST HANOVER, NJ 07936-1080

EXAMINER

DIXON, ANNETTE FREDRICKA

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

08/25/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/714,511	Applicant(s) ALSTON ET AL.	
	Examiner Annette F. Dixon	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on appeal brief (3/1/10) and conf. (6/2/10).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-20, 22-24 and 26-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-20, 22-24 and 26-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to the appeal brief, filed on March 1, 2010, and the appeal conference, held on June 2, 2010, with a decision to reopen. Examiner acknowledges claims 1-9, 11-20, 22-24, 26-47 are pending in this application, with claims 10, 21, and 25 having been cancelled.

2. In view of the Appeal Brief filed on March 1, 2010, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 26-28 and 37-40 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. No amendment may introduce new matter into the disclosure of an application after its filing date. MPEP §608.04. The omitted steps are: providing a puncture method or means by which the pharmaceutical formulation from inside the receptacle is in contact with the inhalation airflow in order to aerosolize the pharmaceutical formulation.

Specifically, claim 26 recites the method steps of "providing a receptacle containing a pharmaceutical formulation" and "inhalation...to aerosolizing the pharmaceutical formulation"; however, the essential steps by which the receptacle is opened to allow for aerosolization are missing. As such, Examiner is unsure if the opening process is a result of a puncture, the splitting of a two part capsule, or if the receptacle is previously opened prior to the placement of the receptacle in the device. Consequently, as this essential element is missing from the claims, it appears the invention as claimed will not work to enable the aerosolization of pharmaceutical formulations contained within a receptacle. From a close review of Applicant's disclosure, it appears the piercing of the receptacle is required, as seen in Figures 4a-4e and claimed in claims 45-47. Thus, this feature must be claimed in order to recite the

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present invention capable of being used in the manner as supported in the original disclosure as filed. Appropriate correction and clarification is required. Dependent claims 27, 28, and 37-40 incorporate the subject matter from which they depend and do not resolve the indefinite nature of the manner by which the receptacle is opened.

5. Claims 1-5, 11-19, 22, 23, and 26-40 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. No amendment may introduce new matter into the disclosure of an application after its filing date. MPEP §608.04. The omitted steps are: providing a puncture method or means by which the pharmaceutical formulation from inside the receptacle is in contact with the inhalation airflow in order to aerosolize the pharmaceutical formulation.

Specifically, claims 1, 15, and 22 recite the apparatus having "a receptacle containing a pharmaceutical formulation" and "a user inhales...to cause the ...pharmaceutical formulation [to] exit"; however, the essential elements or steps by which the receptacle is opened to allow for aerosolization are missing. As such, Examiner is unsure if the opening process is a result of a puncture, the splitting of a two part capsule, or if the receptacle is previously opened prior to the placement of the receptacle in the device. Consequently, as this essential element is missing from the claims, it appears the invention as claimed will not work to enable the aerosolization of pharmaceutical formulations contained within a receptacle. From a close review of Applicant's disclosure, it appears the piercing of the receptacle is required, as seen in

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Figures 4a-4e and claimed in claims 6-9, 20, 24, and 41-44. Thus, this feature must be claimed in order to recite the present invention capable of being used in the manner as supported in the original disclosure as filed. Appropriate correction and clarification is required. Dependent claims 2-5, 11-14, 16-19, 23, and 29-40 incorporate the subject matter from which they depend and do not resolve the indefinite nature of the manner by which the receptacle is opened.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

7. Claims 1-7, 9, 11-13, 15-20, 22-24, 26-31, 33-35, 37-39, 42, 44, 45, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Lax et al. (3,795,244).

As to Claims 1, 15, 22, and 26, Lax discloses an aerosolization apparatus, comprising: a body (10) defining a chamber (the internal housing of the body 10, including the capsule holder 30) having an air inlet (70, Column 4, Lines 30-32) and an air outlet (20, Column 2, Lines 44-48), wherein the chamber (30 via internal portion 32) is sized to receive a receptacle (42, Column 2, Lines 65-67) containing a pharmaceutical formulation in a manner which allows the receptacle (42) to move within the chamber (30, Column 4, Lines 33-54) and wherein the air inlet is oriented to cause air swirl within the chamber (30); wherein the chamber (30) comprising a longitudinal axis which is substantially parallel to an inhalation direction and wherein the chamber (30) has side walls (32) with a cross section orthogonal to the longitudinal axis of the

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chamber that is non-circular (hexagon shape, 32, Figure 5, and Column 2, Lines 55-61), and wherein the receptacle (42) contacts the non-circular cross-section (hexagon shape, Figure 5, and Column 2, Lines 55-61) when the receptacle (42) moves within the chamber, whereby when a user inhales, air enters the chamber through the inlet (70, Column 4, Lines 30-32) to cause the receptacle (42) to move within the chamber (30, Column 4, Lines 33-54) so that the receptacle (42) is disturbed by the contact with the non-circular cross section (hexagon shape, 32, Figure 5, and Column 2, Lines 55-61) of the sidewall and the pharmaceutical formulation exits through an opening in the receptacle (42, via needle 68, Column 3, Lines 42-67) and is aerosolized for delivery to the user (via mouthpiece 12) through the outlet (20, Column 2, Lines 44-48).

As to Claims 2, 16, 23, and 27, Lax discloses the receptacle (42) is a capsule (Column 2, Lines 65-67).

As to Claims 3 and 17, Lax discloses the longitudinal axis of the chamber (30) and the longitudinal axis of the capsule (42) is less than 45 degrees. Specifically, as seen in Figures 1-3 the longitudinal axis of the capsule and the chamber are coplanar and share the same axis through the body of the inhaler.

As to Claims 4, 18, and 28, Lax discloses the chamber (30) is elongated to enable the lengthwise receipt of the capsule (42) into the chamber (30). (Figures 1-3).

As to Claims 5 and 19, Lax discloses the width of the chamber (30) is less than the length of the capsule (42). (Figures 1-3).

As to Claims 6, 7, 20, 24, and 45, Lax discloses a puncture member (needle 68) movable within the chamber (the internal housing of the body 10, including the capsule holder 30) to create an opening in the receptacle (Column 3, Lines 42-67).

As to Claims 9, 42, 44, and 47, please see the rejection of claim 6. Lax discloses only one end of the capsule (42) is pierced. (Figures 1-3).

As to Claims 11, 29, 33, and 37, Lax discloses the non-circular cross section (hexagon shape, 32, Figure 5, and Column 2, Lines 55-61) has projections 38 extending into the chamber. (Figures 1-3).

As to Claims 12, 30, 34, and 38, Lax discloses the non-circular cross section (hexagon shape, 32, Figure 5, and Column 2, Lines 55-61) has indentations (via the apex of 32) inwardly into the sidewalls of the chamber (30).

As to Claims 13, 31, 35, and 39, Lax discloses the non-circular cross section (hexagon shape, 32, Figure 5, and Column 2, Lines 55-61) is a polygon.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 14, 32, 36, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lax et al. (3,795,244).

As to Claims 14, 32, 36, and 40, Lax discloses the non-circular cross section (hexagon shape, 32, Figure 5, and Column 2, Lines 55-61) is a polygon for the purpose of providing a structure that enables movement of the capsule. (Column 4, Lines 33-54). Further, Lax discloses the polygon shape may be replaced without changing the function of the invention. (Column 5, Lines 12-13). Yet Lax does not expressly disclose the shape to be an oval. In light of the relationship between the shape of the chamber and the ability of the capsule to move, it would have been an obvious matter of design choice to make the different portions of the non-circular cross section of whatever form or shape was desired or expedient. A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. In re Dailey et al., 149 USPQ 47. Moreover, Applicant has not asserted that the specific shape of the chamber provides a particular advantage, solves a stated problem, or serves a purpose different from that of providing a means by which the capsule may move within the chamber in order to excise the pharmaceutical formulation from the capsule; thus, the use of this specific shape lacks criticality in its design. Consequently, one of ordinary skill in the art would have expected Applicant's invention to perform equally well with Lax. Therefore, it would have been obvious to one having ordinary skill in the art to modify the shape of the chamber of Lax to an oval for the purpose of enabling the movement of the capsule in the chamber in order to excise the pharmaceutical formulation from the capsule.

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10. Claims 8, 41, 43, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lax et al. (3,795,244) in view of Altounyan (3,507,277).

As to Claims 8, 41, 43, and 46, Lax discloses a single puncturing member (needle 68); yet does not expressly disclose the use of a pair of puncturing members. Altounyan teaches the use of a pair of puncturing members (16 and 16a) for perforating and excising the pharmaceutical formulation from the capsule to the patient, where user has the choice of the number of holes desired in order to perforate and excise the pharmaceutical formulation to best aid in the oral inhalation process (Abstract, Column 2, Lines 1-10). Therefore, it would have been obvious to one having ordinary skill in the art to modify the single puncturing member of Lax to include a second puncturing means, as taught by Altounyan to provide the ability of the user to select the desired number of capsule openings to enable the pharmaceutical formulation to be delivered for inhalation therapy.

Double Patenting

11. Applicant is advised that should claim 1 be found allowable, claims 15 and 22 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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13. Claims 1-9, 15-20, 22-24, 26-28, and 41-47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 13-15, and 18-20 of U.S. Patent No. 7,516,741. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant independent claims 1, 15, 22, and 26 are merely broader than patent claims 1 and 10. It is clear that all of the elements of claims 1, 15, 22, and 26 are found in claims 1 and 10 of the patent. The difference lies in the fact that the patent claims include many more elements and is thus much more specific. Thus, the invention of patent claims 1 and 10 is in effect a "species" of the "generic" invention of instant claims 1, 15, 22, and 26. It has been held that the "generic" invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 1, 15, 22, and 26 are anticipated by claims 1 and 10, it is not patentably distinct from patent claims 1 and 10.

With respect to the claims, the patent recites an aerosolizing device having a housing with an inlet, an outlet, and a chamber for retaining a capsule of pharmaceutical formulation; while the instant claims recites an aerosolizing device having a housing with an inlet, an outlet, and a chamber for retaining a capsule of pharmaceutical formulation.

The limitations of instant claims 2, 16, 23, and 27 are recited in patent claim 1. The limitations of instant claims 3 and 17 are recited in patent claims 7 and 18. The limitations of instant claims 4, 18, and 28 are recited in patent claims 8 and 19. The limitations of instant claims 5 and 19 are recited in patent claims 9 and 20. The limitations of instant claims 6, 7, 20, 24, and 45 are recited in patent claims 1, 2, 10, and

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13. The limitations of instant claims 8, 41, 43, and 46 are recited in patent claims 3 and

14. The limitations of instant claims 9, 42, 44, and 47 are recited in patent claims 4 and

15.

14. Claims 1-5, 15-19, 22, 23, and 26-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 11-15, 18, and 20 of copending Application No. 10/295,783. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant independent claims 1, 15, 22, and 26 are merely broader than copending claims 1, 15, 18, and 20. It is clear that all of the elements of claims 1, 15, 22, and 26 are found in claims 1, 15, 18, and 20 of the copending application. The difference lies in the fact that the copending claims include many more elements and is thus much more specific. Thus, the invention of copending claims 1, 15, 18, and 20 is in effect a "species" of the "generic" invention of instant claims 1, 15, 22, and 26. It has been held that the "generic" invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 1, 15, 22, and 26 are anticipated by copending claims 1, 15, 18, and 20, it is not patentably distinct from copending claims 1, 15, 18, and 20. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

With respect to the claims, the patent recites an aerosolizing device having a housing with an inlet, an outlet, and a chamber for retaining a capsule of pharmaceutical formulation; while the instant claims recites an aerosolizing device having a housing

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with an inlet, an outlet, and a chamber for retaining a capsule of pharmaceutical formulation.

The limitations of instant claims 2, 16, 23, and 27 are recited in copending claim 1, 15, 18, and 20. The limitations of instant claims 3 and 17 are recited in copending claim 12. The limitations of instant claims 4, 18, and 28 are recited in copending claim 13. The limitations of instant claims 5 and 19 are recited in copending claim 14.

Response to Amendment

15. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Response to Arguments

16. Applicant's arguments with respect to claims 1-9, 11-20, 22-24, 26-47 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Baum (4,446,862), Ramella (5,048,514), Dean (4,249,526) and Damani (3,971,377) disclose additional inhaler devices using capsules.

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18. The following reference is NOT prior art; however, it is considered pertinent to applicant's disclosure. Dunkley et al. (7,559,325) discloses the same invention as Applicants with remarkably similar drawings.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Annette F Dixon
Examiner
Art Unit 3771

/Annette F Dixon/

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Examiner, Art Unit 3771

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761